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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,118	01/27/2004	Beat Fluchmann	20722 US1 C038435/0175476	3755
7590	03/01/2005		EXAMINER WEDDINGTON, KEVIN E	
Kevin C. Hooper, Esq. BRYAN CAVE LLP 1290 Avenue of the Americas New York, NY 10104-3300			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,118

Applicant(s)

FLUEHMANN ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/915,152.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 1-19 are presented for examination.

Applicants' preliminary amendment filed January 27, 2004 and the information disclosure statement filed April 26, 2004 have been received and entered.

Applicants' election filed August 19, 2004 in response to the restriction requirement of July 16, 2004 has been received and entered. The applicants elected the invention described in claims 10-13 (Group III) with traverse.

Applicants' traverse of the restriction requirement is not deemed persuasive for reasons set forth in the previous Office action. Therefore, the restriction requirement is hereby made Final.

Claims 1-9 and 14-19 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/915,152, filed on July 25, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating non-insulin dependent diabetes mellitus with phytanic acid only, does not reasonably provide enablement for treating non-insulin dependent diabetes mellitus with a phytanic acid precursor or a derivative of phytanic acid or preventing non-insulin dependent diabetes mellitus with phytanic acid, a phytanic acid precursor, or a derivative of phytanic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treating or prevention non-insulin dependent diabetes mellitus comprising administering to a human or an animal an effective dose of a pharmaceutical composition or dietary supplement

comprising phytanic acid, a phytanic acid precursor, or a derivative of phytanic acid.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

There are no known preventive therapies for non-insulin dependent diabetes mellitus in the art

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The present invention is unpredictable unless experimentation is shown for a phytanic acid precursor or a derivative of phytanic acid to treat non-insulin dependent diabetes mellitus.

The breadth of the claims

The claims are very broad and inclusive of any "cause" of non-insulin dependent diabetes mellitus.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of phytanic acid to reduce the plasma insulin in male Wistar rats (Example 4).

There are no examples showing the phytanic acid, phytanic acid precursors or derivatives of phytanic acid will, in fact, prevent non-insulin dependent diabetes mellitus especially in a human or an animal not presently at risk of or predisposed to developing such a disease or disorder.

Current modes of treatment are known, but there are no known agents which can prevent non-insulin dependent diabetes mellitus.

The quantity of experimentation necessary

Applicants have failed to provided guidance as to how the phytanic acid precursors and derivatives of phytanic acid disclosed in claims 12 and 13 is effective in treating non-insulin dependent diabetes mellitus. The level of experimentation needed to determine these agents would be able to treat NIDDM is undue.

Applicants have failed to provide guidance as to which particular cause would be prevented for non-insulin dependent diabetes mellitus (NIDDM). The skilled artisan would expect that interaction of a particular agent in the

prevention of NIDDM to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification set forth no such understanding or any criteria for extrapolating beyond the administration of phtyanic acid, phytnic acid precursors or derivatives of phytnic acid to treat NIDDM. Even for the data presented, no direction is provided to prevent NIDDM and its causes. Absent reasonable *a priori* expectations of success, one skilled in the art would have to test extensively many conditions that may lead to NIDDM to discover which cause is prevented. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as its is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claims 10–13 are not allowed.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10–13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rendered indefinite and vague because the claim presently reads on a combination of phytanic acid, a phytanic acid precursor and a derivative of phytanic acid into a single composition. Is this correct? The remaining claims 11–13 are rendered indefinite to the extent that they incorporate the above terminology.

Claims 10–13 are not allowed.

To overcome this rejection, the applicants may wish to amend claim 10 to recite a Markush group consisting of phytanic acid, a phytanic acid precursor or a derivative of phytanic acid so that one active agent is selected from the group and not all agents are combined together.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mukherjee et al., "Sensitization of diabetic and obese mice to insulin by retinoid X receptor agonists", Nature, Vol. 386, No. 6623, pp. 407-410 (1997)

(C5 of PTO-1449) in view of Lemotte et al., "Phytanic acid is a retinoid X receptor ligand", European Journal of Biochemistry, Vol. 236, No. 1, pp. 328-333 (1996) (C3 of PTO-1449).

Mukherjee et al. teach retinoid X receptors are well-known to treat non-insulin dependent diabetes mellitus in mice (see the abstract).

The instant invention differs from the cited reference in that the cited reference does not teach the phytanic acid, a phytanic acid precursor or a derivative of phytanic acid is preferred to treat non-insulin dependent diabetes mellitus (NIDDM). However, the secondary reference, Lemotte et al., teaches phytanic acid as a retinoid X receptor ligand (See the abstract). Clearly, one skilled in the art would have assumed the administration of phytanic acid to treat NIDDM is obvious since retinoid X receptors are well-known to treat NIDDM in the absence of evidence to the contrary.

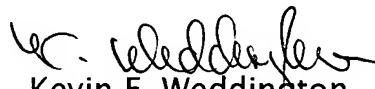
Claims 10-13 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone

number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
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K. Weddington

February 24, 2005